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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/700,936	11/04/2003	Randy S. Bethiel	VPI/02-123 US	5983
27916	7590	07/05/2005	EXAMINER	
VERTEX PHARMACEUTICALS INC. 130 WAVERLY STREET CAMBRIDGE, MA 02139-4242			HABTE, KAHSAI	
			ART UNIT	PAPER NUMBER
			1624	

DATE MAILED: 07/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/700,936

Applicant(s)

BETHIEL ET AL.

Examiner

Kahsay Habte, Ph. D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-24 and 26-29 is/are pending in the application.
- 4a) Of the above claim(s) 26-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2,7,12 and 18-22 is/are rejected.
- 7) ☒ Claim(s) 1,3-6,8-11,13-17,23 and 24 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 4/12/2004.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

1. Claims 1-24 and 26-29 are pending in this application.

### ***Election/Restriction***

2. Applicant's election without traverse of Group I, Claims 1-24 filed on 5/24/2005 is acknowledged. Claims 26-29 are withdrawn from prosecution as non-elected invention.

### ***Information Disclosure Statement***

3. Applicant's Information Disclosure Statement, filed on 4/12/2004 has been acknowledged. Please refer to Applicant's copies of the 1449 submitted herewith.

### ***Claim Objections***

4. Claim 1 is objected to because of the following informalities: the notation for the choices of R<sup>1</sup> and R<sup>2</sup> are not consistent. The notation "I, II, iii, IV, V, VI" is not consistent. It is recommended that applicants use different notations. Appropriate correction is required.
5. In claims 17-18 is objected because of the recitation of "general" in the phrase "general structure of Formula IIIa or IIIb". Since a compound is specific and not "general", it is recommended that applicants delete "general" from said phrase.

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6. In claim 22, the phrase "methylene dioxy" should read as "methylenedioxy".

Appropriate correction is required.

7. In claim 23, the bonds of the "SO<sub>2</sub>" substituent attached to the phenyl ring is not drawn properly. The double bonds from the O to S or the single bond from S to NH<sub>2</sub> are not clear. E.g. the chemical structure of IVa-21-24, IVa-38-39, IVa-50, etc. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 7 12 and 18-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention:

a. In claims 2 and 18, the phrase "R<sup>1</sup> and R<sup>2</sup> taken together represent the heterocycle i" or in claim 19, the phrase "R<sup>1</sup> and R<sup>2</sup> taken together represent the heterocycle I depicted above" is not clear. The phrase lacks antecedent basis. What is structure of the "heterocycle I"? Are applicants referring to the core structure indicated by roman letter "Formula I" or the first choice for R<sup>1</sup> and R<sup>2</sup>? If the latter is intended, it is recommended that applicants draw the chemical structure in claims 2 and 18-19. Note

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that "I" is used to indicate the main core structure and "I" is used to indicate the choices for R<sup>1</sup> and R<sup>2</sup> at page 3.

b. Claim 7 is rejected because it is improperly dependent on claim 1. In claim 7, it has been recited "R<sup>3</sup> is hydrogen", but R<sup>3</sup> is hydrogen is not permitted in claim 1. Likewise, the same problem appears in claim 19.

c. In claims 12, 21 and 22, the phrase "ZR<sup>5</sup> ....aminophenyl" is not clear. What is it? Heterocyclic or carbocyclic? Is it attached to the rest of the molecule thru the amino or thru the phenyl? If it is attached thru the nitrogen, then it is the same as "NHphenyl" that is recited in claims 12, 21 and 22. Note that applicants recited "ZR<sup>5</sup> ...NHphenyl" and it is clear how it is attached to the rest of the molecule and what it is, but not for the choice "ZR<sup>5</sup> ...aminophenyl".

### ***Conclusion***

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kahsay Habte, Ph. D. whose telephone number is (571) 272-0667. The examiner can normally be reached on M-F (9.00AM- 5:30PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Wilson (Acting SPE) can be reached at (571) 272-0661. The fax

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phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Kahsay Habte, Ph. D.  
Patent Examiner  
Art Unit 1624

KH  
June 28, 2005